510(k) Summary

SEP - 6 2000

K 002655

MODEL MD-550
NONINVASIVE BLOOD PRESSURE MEASUREMENT SYSTEM

1. COMPANY INFORMATION.

Name: Meditec Co., Ltd.

Address: #206 Ga dong, Sungnam APT. Factory, 150 Yatap-dong, Bundang-gu, Sungnam-city, Kyunggi-do 463-070, Korea

Phone: (011) 82-31-707-2701 *Contact:* Mr. D. H. Chang, President

2. DEVICE IDENTIFICATION.

Trade name: Model MD-550, Digital Blood Pressure Monitors

Common Name and Classification Name: Noninvasive Blood Pressure Measurement System, 74 DXN

3. PREDICATE DEVICES.

Meditec Digital Blood Pressure Monitor, Model MD-700, K990380

4. DEVICE DESCRIPTION.

General: Meditec Model MD-550 is compact digital blood pressure monitor intended for measurement of blood pressure at the brachial artery. The systems use the oscillometric method of operation. The plug-in type pneumatic cuff with built-in semiconductor strain gauge is automatically inflated by built-in pump. The systems are microprocessor controlled and includes pushbutton operating controls, circuitry to detect and process minute pressure oscillation; a six-digit LCD display of systolic and diastolic pressure readings and heart rate; and a memory function.

Operation: The model utilize a pressure measurement algorithm designed to detect, process, and store pressure readings. The pressure measurement range is 20 to 285 mmHg maintained within limits of 2 of 3 mmHg/sec to optimize measurement accuracy.

Power: The Models MD-550 system is powered by four 1.5-volt size AA batteries. Power is shut down automatically if the unit remains idle for a period of approximately 3 minutes.

5. INTENDED USES.

The Models MD-550 systems are the noninvasive measurement of systolic and diastolic blood pressure and determination of heart rate in adult patients, age 18 and above. Because

the devices are recommended for in a home care environment. use should be limited to patients capable of understanding written and/or oral directions.

6. COMPARISON WITH PREDICATE DEVICES.

The Model MD-550 system has been compared with the Meditec Models MD-700 Digital Blood Pressure Monitor. The intended use of the three systems is the same. The principle operation (oscillometric measurement) and many operating features are identical. The only substantive difference between the subject and predicate devices is that one of predicate device. Model MD-700 device incorporate an air pump. instead of the manual means of cuff inflation. All systems maintain a constant bleed down rate during deflation and measurement through the use if an electronic air release valve. All systems present measurement results digitally on a six-digit LCD and are powered by four 1.5V batteries. All systems offer the measurement range with 20 to 285 mmHg. It is concluded that there are no technologic differences between the subject and predicate devices that raise new questions concerning either safety or effectiveness.

7. PERFORMANCE DATA.

The measurement performance of the Meditec systems have been evaluated in accordance with ANSI/AAMI Standard SP10-1992 and found to comply with the accuracy criteria established in the standard. Safety testing including electrical characteristics of the systems and components. life testing over 10,040 operational cycles. intra-device variability. environmental integrity under various operating and storage conditions including high and low altitude extremes. and resistance to vibration and shock has been conducted with satisfactory results. Similarly. electromagnetic compatibility compliance studies have been conducted by ONETECH Testing & Evaluation Laboratories. and the device was found to comply with all applicable safety and performance standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 6 2000

Meditec Company, Ltd.
c/o Ms. Carole Stamp
510(k) Program Manager
TÜV Product Service
1775 Old Highway 8
New Brighton, MN 55112-1891

Re: K002655
Digital Blood Pressure Monitor, Model MD-550
Regulatory Class: II (two)
Product Code: DXN
Dated: August 24, 2000
Received: August 25, 2000

Dear Ms. Stamp:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this

response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) Number(if known): K002655

Device Number: Noninvasive Blood Pressure Measurement System
Models MD-550

Indication For Use:

Noninvasive measurement of systolic and diastolic blood pressure and heart rate in adult patients. i.e.. age 18 and above. in a home care environment.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH. Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K002655

Prescription Use _____ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)